REMARKS

Claims 1-5, 7, 13-15, 17, 20, and 26 stand rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 29 stands rejected under 35 USC § 102(b) as being anticipated by Melvin et el., U.S. Patent Publication No. 2003/0023132.

Claims 1-4, 20, 26, 29, 34, 43, 59, 60, 68, 69, 71, 75, 78 and 89 stand rejected under 35 USC § 102(b) as being anticipated by Ferrazzi, U.S. Patent Publication No. 2003/0158570.

Claim 34 stands rejected under 35 USC § 103(a) as being unpatentable over Melvin in view of Feld et al., U.S. Patent Publication No. 2004/0002626.

Claim 36 stands rejected under 35 USC § 103(a) as being unpatentable over Melvin in view of Feld, further in view of Cloud, U.S. Patent No. 5,184,482.

Claim 40 stands rejected under 35 USC § 103(a) as being unpatentable over Melvin in view of Stevens et al., U.S. Patent No. 6,125,852.

Claim 80 stands rejected under 35 USC § 103(a) as being unpatentable over Ferrazzi in view of Cloud.

Claims 44, 46, and 59-62 are allowed. Claims 6, 8-12, 16, 18-19, 21-25, 27-28, 30-33, 35, 37-39, 41-42, 45, 47-58, 63-67, 72-74, 76-77, 79 and 81-88 were previously cancelled. Claims 3, 20, and 26 are canceled in this amendment. Claim 90 is a new claim.

Thus, claims 1-2, 4-5, 7, 13-15, 17, 29, 34, 36, 40, 43, 68, 69, 71, 75, 78, 80, 89, and 90 are pending.

PTO-892 Form

Applicant notes that Stevens et al., U.S. Patent No. 6,125,852, was cited in a 35 USC § 103(a) rejection of claim 40 in the May 12, 2009 Office Action. However, Stevens was not listed in a PTO-892 Form. Applicant respectfully requests that the Examiner provide a PTO-892 Form listing the Stevens reference.

Clerical Error

Claims 46 and 62 are currently amended to fix a clerical error.

Rejection of claims 1-5, 7, 13-15, 17, 20, and 26 under 35 USC § 112

Claims 1-5, 7, 13-15, 17, 20, and 26 are rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Regarding claim 1, the Examiner objected to claim element "assisting means operatively associated with the frame . . ." for lack of written description to clearly link or associate the disclosed structure, material, or acts to the claimed function.

Claim 1 is currently amended to recite an apparatus implantable in a heart ventricle comprising a frame configured to engage an inner circumferential periphery of a ventricle and to expand and contract between an expanded state corresponding to a desired end diastolic diameter of a ventricle and a contracted state corresponding to a desired end systolic diameter of the ventricle. Assisting means are operatively associated with the frame for mechanically assisting movement of the ventricle toward both an end systolic diameter during systole and an end diastolic diameter during diastole. The structure, material, or acts corresponding to the assisting means are set forth in specification paragraphs [0067] and [0076].

Thus, for at least these reasons, Applicant respectfully requests reconsideration and withdrawal of the 35 USC § 112 rejection of claim 1.

Claims 3, 20, and 26 have been canceled. Claims 2, 4-5, 7, 13-15, and 17 are dependent from claim 1 and thus are believed allowable for at least the reasons set forth above with regard to claim 1.

Rejection of claim 29 under 35 USC § 102(b) as being anticipated by Melvin et al., U.S. Patent Publication No. 2003/0023132

Claim 29 is currently amended to recite a method of treating cardiac disease comprising surgically accessing a ventricle and inserting within the ventricle an apparatus configured to mechanically assist movement of the ventricle toward both an end systolic diameter during systole and an end diastolic diameter during diastole. The device is attached to a portion of myocardium defining an inner circumferential periphery of the ventricle.

Melvin does not disclose the method as recited in amended claim 29. Specifically, Melvin does not teach inserting within the ventricle an apparatus configured to mechanically

assist movement of the ventricle toward both an end systolic diameter during systole and an end diastolic diameter during diastole.

Thus, for at least these reasons, Applicant respectfully submits that Melvin fails to anticipate claim 29 as amended. Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 29.

Rejections of claims 1-4, 20, 26, 29, 34, 43, 59, 60, 68, 69, 71, 75, 78 and 89 under 35 USC § 102(b) as being anticipated by Ferrazzi, U.S. Patent Publication No. 2003/0158570

Claim 1 has been amended to recite an apparatus implantable in a heart ventricle comprising a frame configured to engage an inner circumferential periphery of a ventricle and to expand and contract between an expanded state corresponding to a desired end diastolic diameter of a ventricle and a contracted state corresponding to a desired end systolic diameter of the ventricle. Assisting means are operatively associated with the frame for mechanically assisting movement of the ventricle toward both an end systolic diameter during systole and an end diastolic diameter during diastole.

Ferrazzi does not disclose the assisting means as recited in amended claim 1. Specifically, Ferrazzi does not teach assisting means operatively associated with a frame for mechanically assisting movement of the ventricle toward both an end systolic diameter during systole and an end diastolic diameter during diastole. The device disclosed by Ferrazzi only assists systolic contraction. Ferrazzi describes its device as follows:

> The said non-linear elasticity allows the device to act as an *aid to systolic function* during the contraction phase; as far as diastolic function is concerned, the same nonlinear law of elasticity means that *the device does not interfere with diastolic function; in fact, although opposing a progressively increasing resistance against dilatation*, the said device does not statically constrict the heart by impeding its expansion within physiological limits . . ..

Ferrazzi, U.S. Patent Publication No. 2003/0158570, Paragraph [0051] (emphasis added).

Thus, for at least these reasons, Applicant respectfully submits that Ferrazzi fails to anticipate claim 1 as amended. Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 1.

Claims 3, 20, and 26 have been canceled. Claims 2 and 4 are dependent from claim 1 and thus are believed patentable over Ferrazzi for at least the reasons set forth above with regard to claim 1.

Claim 29 is currently amended to recite a method of treating cardiac disease comprising surgically accessing a ventricle and inserting within the ventricle an apparatus configured to mechanically assist movement of the ventricle toward both an end systolic diameter during systole and an end diastolic diameter during diastole. The device is attached to a portion of myocardium defining an inner circumferential periphery of the ventricle.

Ferrazzi does not disclose the method as recited in amended claim 29. Specifically, Ferrazzi does not teach inserting within the ventricle an apparatus configured to mechanically assist movement of the ventricle toward both an end systolic diameter during systole and an end diastolic diameter during diastole. As described above with regard to claim 1, the device in Ferrazzi only assists systolic contraction.

Thus, for at least these reasons, Applicant respectfully submits that Ferrazzi fails to anticipate claim 29 as amended. Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 29.

Claim 34 is currently amended to recite a method of treating cardiac disease comprising: surgically accessing a ventricle; inserting within the ventricle a resilient band comprising at least one spring element operatively associated axially with the resilient band to allow axial stretching and compression of the resilient band, the resilient band configured to limit the ventricle to a select end diastolic internal diameter; placing the resilient band into contact with the inner circumferential periphery of the ventricle; and forming the resilient band into a loop of a diameter about equal to an end diastolic diameter of an inner circumferential periphery of the ventricle.

Ferrazzi does not anticipate the method as recited in amended claim 34. Ferrazzi does not teach forming the resilient band into a loop of a diameter about equal to an end diastolic diameter of an inner circumferential periphery of the ventricle. The device in Ferrazzi is not in a relaxed state while at an end diastolic diameter of an inner circumferential periphery of the ventricle. Ferrazzi's device resists diastolic expansion and is in a maximum elastic state during an end diastolic diameter. Ferrazzi describes its device as follows:

> The construction characteristics of the said device also have the advantages of allowing a multiple and modular distribution of the aid to systolic function, *a gradually increasing resilience that is non-linearly related to end-diastolic pressure, from the systolic to the diastolic phase*, thus avoiding greater volumetric constriction and the possible consequence of diastolic interference.

Ferrazzi, U.S. Patent Publication No. 2003/0158570, Paragraph [0046] (emphasis added).

> The device charged with elastic energy will invert its direction of movement *from this point of maximum dilatation and begin to contract*; being sutured to the endocardial wall of the ventricle or running through the myocardial wall, *it will exercise a direct inward force on the wall itself that will aid the contraction of the ventricle (systolic phase).*

Ferrazzi, U.S. Patent Publication No. 2003/0158570, Paragraph [0079] (emphasis added).

Thus, for at least these reasons, Applicant respectfully submits that Ferrazzi fails to anticipate claim 34 as amended. Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 34.

Claim 43 is dependent from claim 34 and thus is believed patentable over Ferrazzi for at least the reasons set forth above with regard to claim 34.

Claims 59 and 60 are dependent from claim 44. Claim 44 was cited as allowable subject matter by the Examiner in the May 12, 2009 Office Action. *See* May 12, 2009 Office Action, page 12, paragraph 36 and page 13, paragraph 41. Thus, claims 59 and 60 are believed patentable, and Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 59 and 60.

Claim 68 is directed to an apparatus implantable in a heart ventricle comprising a resilient band; a spring element operatively associated axially with the resilient band; means for joining the ends of the resilient band into a circle; the resilient band being configured, with the ends joined, to engage an inner circumferential periphery of a ventricle, with the spring element in a relaxed state during diastole of the ventricle; and means operatively associated with the resilient band for limiting the ventricle to a select end diastolic internal diameter.

Ferrazzi does not anticipate the apparatus as recited in claim 68. As described above with regard to claim 34, the device in Ferrazzi is not in a relaxed state during diastole of the ventricle.

For at least the same reason as set forth above with regard to claim 34, Applicant respectfully submits that Ferrazzi fails to anticipate claim 68. Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 68.

Claims 69, 71, 75 are dependent from claim 68 and thus are believed patentable over Ferrazzi for at least the reasons set forth above with regard to claim 68.

Claim 78 is directed to a method of treating cardiac disease comprising providing a resilient band having at least one spring element operatively associated axially with the resilient band to allow axial stretching and compression of the resilient band and means for limiting axial stretching of the resilient band to a select diameter; surgically accessing a ventricle of a heart; placing the resilient band into contact with the inner circumferential periphery of the ventricle; forming the resilient band into a loop of a diameter about equal to an end diastolic diameter of an inner circumferential periphery of the ventricle; and attaching the resilient band loop to the myocardium defining the inner circumferential periphery of the ventricle.

Ferrazzi does not anticipate the method as recited in claim 78. As described above with regard to claim 34, Ferrazzi does not teach forming the resilient band into a loop of a diameter about equal to an end diastolic diameter of an inner circumferential periphery of the ventricle.

For at least the same reason as set forth above with regard to claim 34, Applicant respectfully submits that Ferrazzi fails to anticipate claim 78. Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 78.

Claim 89 is dependent from claim 78 and thus is believed patentable over Ferrazzi for at least the reasons set forth above with regard to claim 78.

Rejection of claim 34 under 35 USC § 103(a) as being unpatentable over Melvin in view of Feld et al., U.S. Patent Publication No. 2004/0002626

Claim 34 is currently amended to recite a method of treating cardiac disease comprising: surgically accessing a ventricle; inserting within the ventricle a resilient band comprising at least one spring element operatively associated axially with the resilient band to allow axial stretching and compression of the resilient band, the resilient band configured to limit the ventricle to a select end diastolic internal diameter; placing the resilient band into contact with the inner circumferential periphery of the ventricle; and forming the resilient band into a loop of a

diameter about equal to an end diastolic diameter of an inner circumferential periphery of the ventricle.

Melvin is cited for disclosing all of the elements of claim 34 except for a loop shaped strap for connecting together the spring elements 721 to form a more rigid structural frame. However, Melvin does not disclose placing a resilient band configured to limit the ventricle to a select end diastolic internal diameter into contact with the inner circumferential periphery of the ventricle. The restraining bars 111 of Melvin, which is the structure of Melvin for limiting expansion of a ventricle, are positioned on the epicardial surface of a heart. Thus, claim 34 is not obvious over a combination of Melvin in view of Feld.

Rejection of claim 36 under 35 USC § 103(a) as being unpatentable over Melvin in view of Feld, further in view of Cloud, U.S. Patent No. 5,184,482

Claim 36 is dependent from claim 34 and thus is believed patentable over Melvin in view of Feld, further in view of Cloud, for at least the reasons set forth above with regard to claim 34.

Rejection of claim 40 under 35 USC § 103(a) as being unpatentable over Melvin in view of Stevens et al., U.S. Patent No. 6,125,852

Claim 40 stands rejected under 35 USC § 103(a) as being unpatentable over Melvin in view of Stevens. Melvin is cited for disclosing all of the claimed invention except for performing a surgical ventricular reduction.

Claim 40 is dependent from claim 29. Claim 29 is currently amended to recite a method of treating cardiac disease comprising surgically accessing a ventricle and inserting within the ventricle an apparatus configured to mechanically assist movement of the ventricle toward both an end systolic diameter during systole and an end diastolic diameter during diastole. The device is attached to a portion of myocardium defining an inner circumferential periphery of the ventricle.

Melvin does not disclose inserting within the ventricle an apparatus configured to mechanically assist movement of the ventricle toward both an end systolic diameter during systole and an end diastolic diameter during diastole, nor does Stevens. Thus, claim 40 is not obvious over a combination of Melvin in view of Stevens.

Rejection of claim 80 under 35 USC § 103(a) as being unpatentable over Ferrazzi in view of Cloud

Claim 80 stands rejected under 35 USC § 103(a) as being unpatentable over Ferrazzi in view of Cloud. Claim 80 is dependent from claim 78. As set forth above with regard to the rejection of claim 78 under 35 USC § 102(b) as being anticipated by Ferrazzi, Ferrazzi does not teach forming the resilient band into a loop of a diameter about equal to an end diastolic diameter of an inner circumferential periphery of the ventricle. Cloud does not teach this element either. Thus, claim 80 is not obvious over a combination of Ferrazzi in view of Cloud.

Conclusion

For the foregoing reasons, reconsideration and withdrawal of the rejection of the pending claims and issuance of a Notice of Allowance are respectfully requested. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefor to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to deposit account No. 19-5117.

Respectfully submitted,

/TD Bratschun/

Date: August 12, 2009

Thomas D. Bratschun, #32,966
Swanson & Bratschun, L.L.C.
8210 Southpark Terrace
Littleton, CO 80120
Telephone: (303) 268-0066
Facsimile: (303) 268-0065

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